PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 378/04071	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IL04/00456	International filing date *(day/month/year)* 27 May 2004 (27.05.2004)	Priority date *(day/month/year)* 25 November 2003 (25.11.2003)
International Patent Classification (IPC) or national classification and IPC IPC: A61B 29/00 USPC: 606/191-198		
Applicant F.D. CARDIO LTD		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 December 2005 (27.12.2005)	10 May 2006 (10.05.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Kevin T. Truong Telephone No. 571-272-3700

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL04/00456

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☐ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-12 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages NONE as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 13-16 received by this Authority on 27 December 2005 (27.12.2005)
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1/10-10/10 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL04/00456

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-32	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-32	NO
Industrial Applicability (IA)	Claims 1-32	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-32 lack novelty under PCT Article 33(2) as being anticipated by Yurek et al. (U.S. 5,662,703).

Yurek et al discloses in figures 1-4, an outer sheath (18) slidingly move in relation to a inner sheath (42) and a balloon inflation tube (28) having a balloon (58) monted on the its distal end, wherein the balloon inflation tube (28) disposed within the outer sheath (18).

Claims 1-32 meet the criteria set out in PCT Article 33(4), and thus the device industrial applicability because the subject matter claimed can be made or used in industry.

378/04071 A01
PCT/IL04/00458 27.12.2005
IPEA/US

CLAIMS

1. A catheter adapted for performing a task at a location inside a lumen, the catheter comprising:

a) an outer sheath;

b) a balloon capable of inflating inside the lumen when the catheter reaches the location; and

c) a balloon inflation tube, which is attached to the balloon and carries a fluid which causes the inflating of the balloon, said balloon inflation tube running through the outer sheath, movable relative to the outer sheath, and stiff enough so that it can be used to push and pull the balloon relative to the outer sheath.

2. A catheter according to claim 1, wherein the inflation tube comprises:

a) a relatively flexible outer balloon inflation tube with a lumen, extending substantially to the tip of the catheter; and

b) a relatively stiff inner inflation tube element, which runs through the lumen of the outer balloon inflation tube and is movable with respect to the outer balloon inflation tube;

whereby moving the inner inflation tube element back from the tip of the catheter makes a distal portion of the catheter substantially more flexible than when the inner inflation tube extends to the tip of the catheter.

3. A catheter according to claim 2, wherein the inner inflation tube element has a lumen which carries the fluid which causes the inflating of the balloon.

4. A catheter according to any of the preceding claims, and including a propulsion compartment located proximal to the balloon, the propulsion compartment comprising an outer tube and an inner tube, said tubes being concentric, wherein one of said outer tube and inner tube can slidingly move in relation to the other of said outer tube and inner tube in response to a pressure exerted thereon by a fluid introduced into one or both of said outer tube and inner tube.

5. A catheter according to claim 4, wherein one of said outer tube and inner tube is the outer sheath, and the balloon inflation tube runs through and is attached to the other of said outer tube and inner tube.

6. A catheter according to claim 5, wherein the outer tube is the outer sheath.

7. A catheter according to claim 5, wherein the inner tube is the outer sheath.

8. A catheter adapted for performing a task inside a lumen, the catheter comprising:

a) a balloon capable of inflating inside the lumen; and

b) a balloon inflation tube which is attached to the balloon and carries the fluid which causes the inflating of the balloon, the balloon inflation tube comprising a relative flexible outer balloon inflation tube which extends substantially to the tip of the catheter, and a relatively stiff inner inflation tube element, which runs through the lumen of the outer balloon inflation tube and is movable with respect to the outer balloon inflation tube;

whereby moving the inner inflation tube element back from the tip of the catheter makes a distal portion of the catheter substantially more flexible than when the inner inflation tube extends to the tip of the catheter.

9. A catheter according to claim 8, wherein the inner inflation tube element has a lumen which carries the fluid which causes the inflating of the balloon.

10. A catheter according to any of claims 1, 2 or 8, wherein the task comprises dilating the lumen.

11. A catheter according to any of claims 1, 2 or 8, wherein the lumen is inside the body.

12. A catheter according to claim 11, wherein the lumen is a blood vessel.

13. A catheter according to claim 12, wherein the catheter comprises a stent.

14. A catheter according to any of claims 1, 2 or 8, wherein the balloon inflation tube comprises stainless steel.

15. A catheter according to any of claims 1, 2 or 8, wherein the balloon inflation tube comprises NiTi.

16. A catheter according to any of claims 1, 2 or 8, wherein the balloon comprises plastic.

17. A catheter according to any of claims 1, 2 or 8, wherein the balloon comprises a polymer.

18. A catheter according to any of claims 1, 2 or 8, adapted for using a guide wire.

19. A catheter according to claim 18, adapted for using an "over the wire" guide wire.

20. A catheter according to claim 18, adapted for using a "rapid exchange" guide wire.

21. A method of positioning a balloon of a balloon catheter in a lumen, the method comprising:

a) positioning the balloon approximately; and then

b) fine adjusting the position of the balloon, said fine adjusting comprising moving an inflation tube of the balloon catheter relative to an outer sheath of said catheter, by manually manipulating said inflation tube.

22. A method according to claim 21, wherein moving the inflation tube relative to the outer sheath comprises moving the inflation tube while keeping the outer sheath stationary with respect to the lumen.

23. A method according to claim 21, wherein positioning the balloon approximately comprises moving the entire catheter through the lumen.

24. A method according to claim 23, wherein positioning the balloon approximately also comprises using hydraulic force.

25. A method according to claim 21, wherein positioning the balloon approximately comprises using hydraulic force.

26. A method according to any of claims 21-25, wherein fine adjusting also comprises using hydraulic force to move the balloon, while keeping the outer sheath of the catheter stationary with respect to the lumen.

27. A method of manipulating a balloon catheter through a lumen comprising both sharply curved portions and partially obstructed straight portions, the method comprising:

a) arranging a moveable stiffening element to extend substantially to the tip of the catheter, when manipulating the tip of the catheter through the partially obstructed straight portions; and

b) arranging the moveable stiffening element to be withdrawn some distance back from the tip of the catheter, when manipulating the tip of the catheter past the sharply curved portions.

28. A method according to claim 27, wherein the stiffening element is located inside a balloon inflation tube of said catheter.

29. A method according to claim 27, wherein the stiffening element comprises a balloon and a balloon inflation tube of said catheter, and arranging the stiffening element to be withdrawn some distance back comprises withdrawing the balloon into an outer sheath of said catheter.

30. A catheter according to claim 13, wherein the stent is located at substantially the same axial extent of the catheter as the balloon in a configuration suitable for inserting of the catheter into the lumen.

31. A catheter according to claim 13, wherein the stent is adapted to move with the balloon inflation tube when moved relative to the outer sheath.

32. A catheter according to claim 13, wherein moving the balloon inflation tube distally telescopically extends the length of the catheter.